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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/843,941

Applicant(s)
Hemerick et al.

Examiner
Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 13, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 5-9, 11-13, 15, 16, 19-23, 25, 26, 29-33, 35, 36, 39-43, and 45-52 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 45, and 47-52 is/are allowed.
- 6) ☒ Claim(s) 2, 5-9, 12, 13, 15, 16, 19-23, 25, 26, 29-33, 35, 36, 39-43, and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 2, 5-9, 12, 15, 16, 19-23, 25, 26, 29-33, 35, 36 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Burns (5,100,381). As to claims 5, 19, 29 and 39, Winston et al. show outer tubular structure 20, inner elongated structure 12, stent accommodating area (just distal to flange 14) and a plurality of external tubular structure contact areas (flanges 14) which slide against the interior surface of the outer tubular structure 20 since they are shown contacting one another in figures 1, 2 and 4. Winston et al. fail to disclose each subsequently proximal external structure 14 increasing in durometer. However, Burns teaches that the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability (col. 2, lines 30-34 and col. 3, line 65 to col. 4, line 6). It would have been obvious to make the distal portion of the Winston et al. catheter 12 more flexible than the proximal portion so that it too would have this advantage. With this modification, the distal portion of the Winston et al. catheter 12 (which includes a distal flange 14) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 12 (which includes a proximal flange 14) made of a high durometer, stiffer material. As to claims 2, 16, 26 and 36, Winston et al. fail to show Pellethane as the material for the

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inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification. As to claim 35, retracting the Winston et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it is well known in this art to so retract and reposition stents for this reason.

Claims 13 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Burns (5,100,381) as applied to claims 5 and 39 above, and further in view of Hofmann et al. (5,810,837). Winston et al. fail to disclose a gap between an external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20. However, Hofmann et al. teach that there should be a gap between the external surface of the external tubular structure 10 and the inner surface of the outer tubular structure 3 (the outer diameter C of member 10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm as indicated in col. 4, line 38) apparently in order to insure that the inner elongated structure 10, 9, 7 is able to slide relative to outer tubular structure 3 with minimal friction. It would have been obvious to provide such a gap between the Winston et al. external surface of

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the external tubular structure 14 and the inner surface of the outer tubular structure 20 so that it too would have this advantage.

Claims 11, 45 and 47-52 are allowed.

Applicant's arguments filed May 13, 2003 have been fully considered but they are not persuasive. As to claims 5-9, 19-23, 29-33 and 39-43, although it is the Burns outer tube that includes different materials to vary the flexibility of the catheter, Burns never the less teaches that a distal portion of a catheter should be more flexible than the proximal portion by making a distal portion of the catheter of a different material than a proximal portion of the catheter. It would have been obvious to make the distal portion of catheter 12 of Winston et al. more flexible than the proximal portion by making the distal portion of the catheter of a different material than the proximal portion of the catheter in view of this teaching so that it too would have the advantage of allowing the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability. Since the entire distal portion of the Winston et al. catheter 12, including the distal portion of the shaft 12 as well as the distal flange 14 (rather than only distal flange 14) would have different durometer measurement than the proximal portion, including the proximal portion of the shaft 12 as well as the proximal flange 14, by following the Burns teaching, the distal portion of catheter would,

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in fact, be made more flexible than the proximal portion in an appreciable way.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are

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(703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
May 30, 2003



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731